

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON WAVE 3 CASES LISTED IN
EXHIBIT A TO PLAINTIFFS' NOTICE OF
ADOPTION

JOSEPH R. GOODWIN U.S. DISTRICT
JUDGE

**SUPPLEMENTAL RESPONSE AND NOTICE OF ADOPTION OF PRIOR DAUBERT
RESPONSE REGARDING TIMOTHY ULATOWSKI FOR WAVE 3**

Defendants hereby adopt and incorporate by reference the *Daubert* response filed in relation to Timothy Ulatowski for Ethicon Wave 1, Dkt. 2134. Defendants respectfully request that the Court deny Plaintiffs' motion, for the reasons expressed in the Wave 1 response briefing.

In its Wave 1 Order, the Court did not address Mr. Ulatowski's reliability or qualifications, instead excluding or reserving ruling on the admissibility of Mr. Ulatowski's testimony in the "Recurring Issues" section of the Order. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493646, at *2 (S.D. W. Va. Aug. 25, 2016). Ethicon respectfully requests that this Order be reconsidered and that Plaintiffs' motion be denied.

In the Wave 1 Order, the Court stated that it had "repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs . . . a position that has been affirmed by the Fourth Circuit." *Id.* at *3. As set forth in Ethicon's Response in Opposition to Motion to Exclude Mr. Ulatowski for Wave 1 [Dkt. 2134, pp. 3-5], it is incorrect to say that the 510(k) clearance process at issue in this case does not concern safety and efficacy.

Further, as explained by Mr. Ulatowski, the record here presents distinctions never presented to this Court or the Fourth Circuit in the *Bard* litigation, chief among them that *Medtronic v. Lohr* involved a different statute and a different type of predicate than what was

before the Supreme Court in *Medtronic v. Lohr*. This case does not involve “grandfathering” based on a pre-1976 predicate, but rather it involves clearance in which the predicate devices were classified by medical panels based on their safety and effectiveness. For that reason, the finding of “equivalence” in this case was, as Congress, the FDA, and the U.S. Supreme Court have said, a finding that provided reasonable assurance of safety and effectiveness.

But even setting that aside, Mr. Ulatowski’s opinions rest in part on FDA actions outside of the 510(k) clearance process, as explained further in Ethicon’s Wave 1 response. This includes not only the 1988 classification of all surgical mesh and the 2011 medical panel review of surgical mesh but the history of specific language in the Ethicon IFUs which Plaintiffs now challenge. If, for example, Plaintiffs are going to be allowed to question Ethicon’s use of the phrase “nor is [Prolene] subject to degradation or weakening of the tissue enzymes,” then Ethicon is entitled to prove that this language was not just cleared but was actually approved by the FDA in 1988.

This Court’s *per se* exclusion of all FDA testimony is particularly inappropriate with respect to general expert testimony in a “Wave” of cases. This ruling operates as a blanket exclusion as a matter of law because it applies no matter what the state law is and no matter what the factual dispute is to which Mr. Ulatowski would testify. The Court cannot conduct a Fed. R. Evid. 403 balance in the abstract without knowing either the applicable law or the particular fact that is in issue. Relevance cannot be denied when many state statutes and common law decisions specifically hold that FDA evidence is relevant and admissible in product liability cases. In addition, if Plaintiffs make an issue of the degradation language quoted above, there would be no valid Rule 403 objection in many if not all states to Ethicon’s proof that the FDA medical panel

in 1982 found little evidence of mesh degradation and the FDA had actually approved that language for suture in 1988. These are matters touched on in Mr. Ulatowski's testimony.

For these reasons, and those stated in Ethicon's Wave 1 briefing [Dkt. 2134], Plaintiffs' motion to exclude the opinions of Mr. Timothy Ulatowski in Wave 3 should be denied.

Respectfully submitted,

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC.; ETHICON, LLC; AND
JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

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